GUIDELINES

Legislation on the control of pesticides

Food and Agriculture Organization
of the United Nations

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GUIDELINES FOR LEGISLATION

ON THE CONTROL OF PESTICIDES

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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1. INTRODUCTION

These Guidelines, a revision of those which were first published in 1969, are intended to give guidance to Governments wishing to develop a legal framework for the control of pesticides or wishing to review and possibly strengthen existing pesticide control legislation.

For the purpose of these Guidelines the term legislation includes the Statutes enacted by the National Legislative body - Acts, Laws, Ordinances -, and the Subordinate enactments such as Regulations, Decrees, Rules, Notices, and other relevant legal instruments, passed by the Government or an autonomous body.

Legislation must be designed to be able to deal effectively with specific problems applicable in the country. Although a general framework can be suggested, as is done in these Guidelines, in the normal course of events good pesticide legislation must take account of the economic and social situation of the country as well as any specific technical requirements such as the crops grown, pest problems, dietary patterns, toxicity of the required pesticides, level of literacy, climatic and environmental considerations.

In introducing a national pesticide control scheme and the legislation necessary for that scheme, it is important to take into consideration the current and future ability of the country to operate the scheme, the legal framework and the degree of support which the government of the country is able to provide.

Developing countries should design procedures suited to their own specific needs and not necessarily adopt all the elements of a regulatory scheme as may be in operation in another country, particularly a developed one. However, all countries in which pesticides are used should have an effective pesticide registration and control scheme in operation. Such a scheme can assist in ensuring that pesticide use does not result in unreasonable risk to man, livestock and the environment.

2. DEFINITIONS

The following definitions should be considered for incorporation into any pesticide legislation:

- active ingredient means the biologically active part of the pesticide present in a formulation.

- adjuvant means any adhesive, deposit builder, emulsifying agent, spreading agent, synergist or wetting agent intended to be used as an aid to the application and/or effect of a pesticide.

- advertising means the promotion of the sale and use of pesticides by print, electronic media, signs, displays, gift, demonstration or word of mouth.

- advisory committee means the committee that advises the Registrar on any matter pertaining to pesticide registration and control.

- banned means a pesticide for which all registered uses have been prohibited by final government regulatory action, or for which all requests for registration or equivalent action for all uses have, for health and environmental reasons, not been granted.

- common name means the name assigned to a pesticide active ingredient by the International Standards Organization or adopted by national standards authorities to be used as a generic or non-proprietary name for that particular active ingredient only.

- confidential means something spoken or written in trust.

- distinguishing name means the name under which the pesticide is labelled, registered and promoted by the manufacturer and which, if protected under national legislation, can be used exclusively by the manufacturer to distinguish the product from other pesticides containing the same active ingredient.

- formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users.

- label means the written, printed or graphic matter on, or attached to, the pesticide; or the immediate container thereof and the outside container or wrapper of the retail package of the pesticide.

- manufacture means the production, by a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it), of a pesticide active ingredient or preparation of its formulation or product.

- pesticide means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products, or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

- pictogram means a symbol which conveys a message without words.

- proprietary means of a proprietor.

- provisional clearance means an authority given by the Registrar to allow use, or sale as the case may be, on a limited basis and under stipulated conditions for the purpose of obtaining information needed before registration will be considered.

- Registrar means the person appointed by the responsible Minister, or Ministers to administer the pesticide legislation on his behalf.

- registration means the process whereby the responsible national government authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the purposes intended and not unduly hazardous to human or animal health or the environment.

- responsible authority means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and more generally for implementing pesticide legislation.

- severely restricted - a limited ban - means a pesticide for which virtually all registered uses have been prohibited by final government regulatory action but certain specific registered use or uses remain authorized.

3. SCOPE OF LEGISLATION

3.1. Purpose of Legislation

The purpose of legislation on the control of and use of pesticides is to enable society to obtain the benefits from their use with minimal adverse effects to man and the environment.

The provisions of any pesticide legislation should, as recommended in the International Code of Conduct on the Distribution and Use of Pesticides,([1]) be concerned with all aspects of the control of pesticides. These include control of imports, sale and distribution and use of pesticides as well as post-registration activities of marketing, training, licencing, certification and enforcement. The major aspects of each of these activities are discussed in these Guidelines.

A national authority which may be designated by the legislative statute to exercise control over pesticides should be given all necessary powers in that legislation, to enable it to carry out its activities. This may include, inter alia, power to issue subordinate enactments, such as Notices, Rules and guidelines relating to

pesticides. It is desirable that all pesticides covered in paras 3.2 - 3.5 should be controlled by the one responsible authority.

3.2. Agricultural Pesticides

Pesticides for use in agriculture, horticulture, forestry and for use for the control of pests of stored products should be covered by the legislation. Also pesticides and animal remedies used for the control of veterinary pests and diseases may also be included.

3.3. Household Pesticides

Pesticides for the control of household pests should be controlled under the legislation, including household sprays, aerosols, insect coils, smoke generators, and rodenticides for home use.

3.4. Public Health Pesticides

Pesticides used for public health programmes should also be subject to legislative requirements of a pesticide control scheme.

3.5. Industrial Use Pesticides

In some countries it may be a requirement that industrial pesticides also, be subject to the same types of control as required for other pesticides. Examples of industrial use pesticides would include wood preservatives, pesticides in paints, anti-fouling agents, and pesticides used in water cooling towers.

3.6. Exclusions

3.6.1. Nutrients : The provisions of pesticide legislation should not apply to plant nutrients, trace elements, nutritional chemicals, or plant inoculants.

3.6.2. Soil conditioners : Soil conditioners should not be covered in the legislation.

3.6.3. Human/animal drugs : These agents should not be covered unless it is the policy of the country to include animal drugs in the legislation.(see para 3.2 above)

3.6.4. Adjuvants : It is not envisaged that adjuvants, which are sold separately to the pesticide should be required to be registered before they are sold, but some countries may wish to do this, especially if it is claimed that the adjuvant enhances the effectiveness of a pesticide. That decision should be left to the individual country.

Manufacturing, repackaging and transport do not need to be brought within the pesticides law if already covered by existing chemical products legislation as the risks presented are similar to those of other chemical products and should, therefore, be covered by appropriate legislation. In the absence of such legislation, however, consideration may be given to including some of these elements in the

pesticide legislation. On the other hand pesticides resulting form such manufacturing or repackaging must be controlled by registration to ensure that they are approved pesticides and are of acceptable quality.

4. IMPORTANT FEATURES OF LEGISLATION

4.1. Organization and Administration

4.1.1. Responsible authority

4.1.1.1. Primary authority : The primary authority to deal with the registration and control needs to be identified. In most countries this responsibility is given to the Ministry of Agriculture, in some countries it may be the Ministry of Health, in others the Ministry of the Environment. It is desirable that the responsibility of decision making is not vested in any one individual or agency but is collectively made by representatives from several agencies preferably that of government.In some cases a special authority may be established to control pesticides.

Legislation to control pesticides should also require that all pesticides, before they are imported, formulated, packed, labelled, sold or given as a sample, offered for sale, or used, must have either;

a) provisional clearance,(including experimental clearance or permit), or;

b) registration, granted by the responsible authority.

4.1.1.2. Subsidiary authorities:

Customs Agency : This agency has an important role to play to prevent the importation of pesticides which have not been cleared for use via the registration process. It is important that countries are able to control the entry of pesticides into their territories. (See para 4.4).

Extension Services : Extension Services have an important part to play in educating users on pesticide use. Recommendations for use should not be contrary to claims on the approved label.

Health Agency : This agency has a major part to play in promoting safe use practices and in informing medical personnel of correct methods of treatment in the event of pesticide poisoning. Records should be kept of cases of pesticide poisoning which will be of considerable use in monitoring pesticide hazards under actual use conditions. This can lead to modification or restriction of handling, or even to cancellation of the registration.(See para 4.9).

Environment Agency : Effects of pesticides on the environment should be able to be monitored and any unacceptable adverse effects notified so that, if required, use practices can be modified or even banned or severely restricted.

Other Agencies : The government may designate any other subsidiary agency which it deems necessary in the performance of any of its functions.

4.1.2. Advisory/Technical Committees

The legislation should permit the establishment of the mechanisms to enable the pesticide control functions to be carried out through Advisory Committees, Technical Committees or any other means as may be appropriate.

4.1.2.1. Functions of Each : The functions of these committees may range from policy making, to reviewing the technical aspects of applications for registration. The responsibilities of each type of committee must be spelt out clearly in the legislation.

4.1.2.2. Composition of Membership : Membership should consist of experts in various fields such as efficacy, toxicology, chemistry and environmental impacts. Members from various interest groups, such as sellers, users, environmentalists, consumers and government officials, may be considered advantageous in order that the views of all sectors on pesticide control issues are taken into account.

4.1.3. Inspectors and Analysts

To enable the law to be enforced it will be necessary to appoint inspectors and in countries where there is the capability or legal need to analyze formulations the appointment of an official analyst will also be necessary. Appointment of such people will be necessary to enable post-registration activities such as those suggested in the Guidelines on Post-Registration Surveillance and other Activities in the Field of Pesticides ([1]) to be carried out.

4.1.3.1. Responsibilities : Inspectors should have the responsibility to see that the requirements of the law are carried out. In addition they should carry out regular inspections. The inspector should also have the responsibility of ensuring that any sampling of product that is carried out in such a way that it will be valid in a court of law, in the event of a prosecution. The sampling requirements should be described in the legislation. The analyst should be required to receive samples and analyze them in the prescribed manner.

4.1.3.2. Powers : Powers to be given to inspectors and analysts will need to be specified in the legislation. In the case of inspectors, for example, powers need to cover such things as the right of entry into premises, the taking of samples for analysis, confiscation of product, inspection of records, assessing fines and other similar activities.

4.1.4. Fees

There should be provision to set fees for the various activities specified in the legislation. Such fees could, for example cover applications for registration, approval of containers, analysis of formulations or any other activities which the Government decides to charge for.

4.1.5. Appeal procedures

The legislation should include provisions for appeals; the applicant for registration to appeal any decision by the responsible authority for example if registration of a pesticide, or a provisional clearance is not granted. Also there should be provision for appeals to be made against any other decisions made by the responsible authority. Provisions for an appeal can be channeled either through the normal legal system operating in the country if appropriate, or else there may be a need to make specific provisions in the pesticide legislation to allow for this eventuality.

4.2. Registration

4.2.1. Procedures

The procedure for obtaining registration or a provisional clearance should be described in the legislation in order that the applicant for registration is aware of what is required. The registration requirements should cover two situations, namely;

(a) in the case of a pesticide which has not been previously marketed, an application for registration or a provisional clearance should be required, or;

(b) where a pesticide already registered or which has a provisional clearance, an application for a change in a label claim or an upgrading in the clearance status should be provided for.

4.2.2. Who may Apply

The legislation should clearly specify who may apply for registration. The applicant is usually the person or company who wishes to sell, import or manufacture a pesticide for sale, under his own distinguishing name either direct to the user or to a second party for resale, or, who arranges for these activities to be done on his behalf.

4.2.3. Application

Provision should be made in the legislation for the application for registration to be made to the responsible authority on a specified form.

4.2.4. Data Requirements

The application for registration should include all or most of the following data as may be appropriate. Refer to the FAO Guidelines for the Registration and Control of Pesticides ([1]) for information on how much data should be submitted. The legislation should list, in general terms, the data which should be submitted to the responsible authority as part of the application for registration and should include the following:

(a) the proposed distinguishing name of the formulation;

(b) a statement of the composition, including all ingredients, and the chemical identity(ies) of the active ingredient(s), and methods of analysis of the formulation;

(c) adequate toxicological data concerning the active ingredients;

(d) reports of efficacy trials to support the proposed uses;

(e) reports of residue trials following the proposed use on crops intended for human or animal consumption, and the methods of analysis for determining residues on these crops;

(f) reports of environmental effects following the use of the proposed formulation at the proposed rates;

(g) information on disposal methods for the used container and any surplus pesticide.

(h) a copy of the proposed label.

4.2.5. Proprietary/Confidential Information

All the information which is to be submitted by the applicant for registration must be treated as proprietary data by the responsible authority. In addition some of the information may also be confidential. The type of information which is confidential should be clearly stated in the legislation and may include manufacturing process, formulation details and special quality control programmes.

4.2.6. Labelling

It should be a requirement in the legislation that before a pesticide can be sold or offered for sale, or given as a free sample, a label which has been approved by the responsible authority must be firmly affixed to the package. The approved label should contain, inter alia the following information, which should be set out in the legislation.

(a) the distinguishing name of the product,

(b) the names of all the active ingredients using their common name(s);

(c) directions for use as approved by the responsible authority;

(d) warning and cautionary statements, including where required signs and symptoms of poisoning and information on appropriate safety, health and first aid measures;

(e) instructions on disposal of used pesticide containers and information on disposal of spills, as may be required;

(f) any appropriate warning symbols/pictograms;

(g) the registration number;

(h) the name and address of the holder of the registration certificate or, of the provisional clearance;

(i) the date of formulation and the batch number:

(j) any other statement that may be required under the pesticide law or other applicable national legislation.

Reference should be made to FAO Guidelines on Labelling and Pictograms for Pesticide Labels ([1]),([1]), for further detailed information.

The size of the label as well as the languages to be used, and the system of weights and measures to be used in labelling may be set out in legislation. Any such legislation should be consistent with any applicable internationally accepted labelling standards, and with general labelling requirements under any other legislation which may be in force in the country.

4.2.7. Packaging/Approval of Containers

The legislation should allow the Registrar to specify the technical requirements for safe and effective packaging of pesticides. Reference should be made to the FAO Guidelines on this subject ([1]). Any requirements in the legislation should take account of any relevant national requirements, or of any international standards on the subject. If the national Government has required approval of the types of containers into which pesticides are to be packaged and offered for sale, there will need to be provision in the legislation to enable the responsible authority to do so.

4.2.8. Special Restrictions

Legislation may contain special provisions with regard to substances or operations which present a high or unusual degree of hazard and may include the authority to:

(a) prescribe conditions for field evaluation of experimental compounds of such substances;

(b) temporarily prohibit the importation, sale, distribution and use of such substances, even if they are registered;

(c) restrict the importation, sale and distribution of such substances to ensure their use by only authorized organizations or persons;

(d) make any other provisions concerning marketing and/or distribution of such substances, as may be necessary to safeguard third parties, the environment and wildlife resources other than such noxious plants and animals whose control is desired.

4.2.9. Registration Decision

The legislation should require the Registrar to make a timely decision on the application, after considering the evidence. The decision may be to:

(a) accept a pesticide for registration, or

(b) issue a provisional clearance, or,

(c) hold the application until further data requested from the applicant are provided, or,

(d) reject the application.

When registration is granted a certificate of registration should be issued, to which is attached either a copy of the printers pull of, or a final copy of the accepted label. This should be a requirement in the legislation. No change should be allowed to be made to the label without the approval of the responsible authority.

Registration may be granted for a specified period. Some countries may wish to regularly review registrations, others may grant registration with no time limits provided that the legislation gives them the power to review the status of a product at any time. Any provisional clearance, however, should only be granted for a specified time after which it should be cancelled, unless data are supplied to upgrade the claim or a valid reason is given in support of a request for an extension at or before the expiry of the specified time period.

4.2.10. Review and Additional Control

The law should provide for the responsible authority to review the registration or provisional clearance in the light of subsequent knowledge about any unfavourable or unforeseen side effects arising from the normal use of the pesticide. Such information may come from reports of additional testing, reports of poisoning cases, deleterious effects on the environment, phytotoxicity to the host plant or notification of control actions in other countries. Likewise there must be authority in the legislation for the responsible authority to require additional conditions for the manufacture, handling including application of a pesticide or even to revoke that registration, or provisional clearance where it has been determined from the review that the continued use of the pesticide is not desirable, for technical reasons. If a pesticide is banned or severely restricted FAO should be notified as soon as practicable after the action has taken place.(see para 4.4.1). Disposal of any pesticide stocks remaining after any stop sale order is put into effect should be the responsibility of Industry.

4.3. Maximum Residue Limits

In many countries the responsibility for setting maximum residue limits (MRL's) lies with the Health Ministry, but in others where there are no procedures established for setting MRL's this could be

covered by the pesticide control legislation, preferably in consultation with the national authority responsible for food quality.

4.3.1. Who may Apply

The applicant for an MRL would usually be the same person as the applicant for registration, but in some cases research workers may make an application to the responsible authority.

4.3.2. Application

Application should be made supplying the details as outlined in the FAO Guidelines on Pesticide Residue Trials to provide Data for the Registration of Pesticides and the Establishment of Maximum Residue Limits ([1]).

4.3.3. Procedure

Application should be made to the responsible authority.

4.3.4. Data Requirements

The information described in the Guidelines (Ref 7) should be submitted.

4.4. Control of Imports

The legislation should provide that no importation of pesticides should be allowed without an appropriate permit from the responsible authority. All countries should develop infrastructures to enable them to control imports of pesticides. The responsible authority should coordinate with the Customs Agency in the exercise of this responsibility.

4.4.1. Prior Informed Consent

Where a country has elected to join the Prior Informed Consent (PIC) scheme run by FAO, it should be in a position to evaluate the information supplied to it and to make a decision on the merits of allowing the import of the pesticide in question. Where there is a registration scheme in operation decisions on whether or not to allow import will be determined by whether or not the pesticide is registered. The information must be evaluated as quickly as possible. If the importation is refused the Customs Agency must be given powers to refuse entry.

4.4.2. Domestic Control

A country may refuse to allow the importation of a pesticide which is in the PIC procedure and which is either registered in, or if there is no scheme, in use in the country. If this is the case there should be provision in the legislation to require the country to be able to restrict its own domestic use and or production of the pesticide concerned.

4.5. Licensing and Certification

Some countries may wish to provide for the licensing of various groups of people associated with the manufacture, formulation, repacking, importation, distribution, sale and application of pesticides.

4.5.1. Manufacture, Formulation and Repackaging

Licensing of these groups provides the Government with an assurance that the persons are aware of the hazardous nature of the products they are dealing with and requires that they take the responsibility of complying with the legislation in force. There should be provision in the legislation to enable licensing of manufacturers, formulators and repackers to be undertaken. This may require regular training programmes, inspections, examinations and spot checks to be made.

4.5.2. Importers

There should be a provision in the legislation to license importers of pesticides and ensure that only registered pesticides are imported.

4.5.3. Dealers and Distributors

There will need to be provision in the legislation to license pesticide dealers and distributors. Licensing requirements could cover the provision of proper facilities for storage and display for sale, a knowledge of the properties of the products they are selling, actions to be taken in cases of emergency such as fire, flood, leakage or spillage of pesticides, poisoning of people or animals, the requirements to keep adequate records are some of the factors which need to be considered before a licence is granted. The premises will need to be inspected from time to time by competent authorities following the Guidelines on Retail Distribution with Particular reference to storage and Handling at the Point of Supply to Users in developing Countries ([1])

4.5.4. Commercial Applicators

If countries have the infrastructure to operate a licensing or registration scheme for persons applying pesticides for hire or reward, such as, for example, pest control operators, the power to enable this to be done will need to be included in the pesticide legislation. Any licensing scheme for commercial applicators is designed to ensure safety of applicators and their clients, generate awareness of the inherent risks of indiscriminate use and misuse of pesticides and to enable early recognition of pesticide poisoning.

4.6. Advertising

Any claims made in the advertising of a pesticide should not be in conflict with, or at variance to those claims accepted by the responsible authority. Only pesticides which are registered may be advertised. In some cases the country may wish to prevent the

advertising of those pesticides which have a provisional clearance. The legislation should make it an offence if a conflict occurs. The International Code of Conduct sets out some standards for advertising in Article 11 which should be followed.

4.7. Record Keeping and Reporting

The legislation should require that persons dealing in pesticides keep records for a specified period and for their books and records to be available for inspection by Inspectors at all reasonable times.

4.8. Enforcement : The legislation should prescribe the offences and penalties under the legislation.

4.8.1. Offences

Any pesticide legislation should have provision to make it unlawful for any person or corporation to carry out a number of operations such as:

(a) to sell or distribute a pesticide which is not registered or which has not been given provisional clearance by the responsible authority;

(b) to sell or distribute a pesticide without an approved label attached to it;

(c) to sell or distribute a pesticide which does not meet the specifications as stated when the product was registered;

(d) to detach, alter, deface or destroy any label on the container of a pesticide product;

(e) to repackage or transfer the contents of a pesticide product unless the new container is labelled with an approved label and unless the operation is carried out in licensed premises;

(f) to advertise a pesticide which either, is not registered or which has a provisional clearance, or in manner that is misleading or inaccurate:(Refer to Article 11 of The International Code of Conduct on the Distribution and Use of Pesticides (Ref 1).

(g) to supply a pesticide which is packaged a container which has deteriorated, or has been damaged so as to be dangerous in storage or transport, or when opened for use;

(h) to use a pesticide in a manner which is not consistent with the conditions on the approved label.

(i) to make false statements or provide false information in the application for registration, or licensing and certification or in required reports or records;

(j) to knowingly release confidential information.

4.8.2. Penalties

Any offence prescribed in the pesticides legislation should take into account the requirements in any other relevant national legislation. Fines and any other penalties for breaching the requirements of the legislation should be detailed in the legislation. Other penalties may include suspension or revocation of licenses, cancellation of registration or criminal prosecution.

4.9. Monitoring

4.9.1. Types and Purposes

The legislation should provide the responsible authority with powers to carry out post-registration monitoring to enable it to measure the effects of pesticide use. Inspectors will have powers to do this work but it should be a requirement of the legislation that it be carried out. Such monitoring requirements may include the quality of the formulations on the market, whether or not pesticides are being used in accordance with label directions, pesticide residue levels in food, environmental impact of pesticide use and accidental poisoning from pesticide use, and hazards in handling and application.

4.10. Training

4.10.1. Applicators and Users

The responsible authority should have power in any legislation to become involved with the training programmes for applicators and users. This may be in association with licencing or it may not.

4.10.2. Medical Practitioners

In some countries where there is the opportunity to establish a medical training facility it is may be useful to have this established under the legislation, or other relevant laws on public health and safety.

4.10.3. Dealers and Distributors

Retail shops for pesticides are important channels of information to farmers on the safe handling and effective use of pesticides. Training of shop owners staff will go a long way in ensuring safe use at farm level. In addition dealers should be trained in the proper handling, storage, display for sale, record keeping as my be required under the licensing laws. Thus there should be a requirement in the legislation to enable dealer training be carried out.

4.11. Binding Provisions

Any legislation on pesticide registration and control should be binding on the government of the country responsible for the implementation of that legislation.

5. REFERENCES.

1. International Code of Conduct on the Distribution and Use of Pesticides, FAO, Rome 1986

2. Guidelines on Post-Registration Surveillance and Other Activities in the Field of Pesticides, FAO, Rome 1988

3. Guidelines for the Registration and Control of Pesticides, FAO, Rome 1985

4. Guidelines on Good Labelling Practice for Pesticides, FAO, Rome 1985.

5. Pictograms for Pesticide Labels, FAO, Rome 1988.

6. Guidelines for the Packaging and Storage of Pesticides, FAO, Rome 1985.

7. Guidelines on Pesticide Residue Trials to Provide Data for the registration of Pesticides and the establishment of Maximum Residue Limits, FAO, Rome 1986.

8. Guidelines on Retail Distribution of Pesticides with Particular Reference to Storage and Handling at the Point of Supply to Users in Developing Countries, FAO, Rome 1988

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